Remarks

Responsive to the Office Action of January 28, 2004, please cancel claims 94-95 and 125-132. Claims 125-132 are canceled in response to the restriction requirement, and the cancellation of claims 125-132 is not made for reasons of patentability, and should not be viewed with prejudice to the content of these claims. Claims 81-93 and 96-124 remain pending in the application.

In the Office Action of January 28, 2004, claims 81-125 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of co-pending Application No. 09/912,494. Applicants previously erroneously filed a terminal disclaimer over U.S Patent Application Ser. No. 09/912,424. Please disregard the previously filed terminal disclaimer. Applicants have filed a terminal disclaimer directed to U.S. Patent Application Ser. No. 09/912,494 with this response to overcome the rejection.

In the Office Action of January 28, 2004, claims 94 and 95 were rejected under 35 USC §112, second paragraph. Claims 94 and 95 have been canceled.

In the Office Action of January 28, 2004, claims 81-125 were rejected under 35 USC §102(b) as being anticipated by EP 0 380 343. Applicants respectfully traverse the rejection.

Claims 94, 95, and 125 have been cancelled, claim 125 having been cancelled in response to the restriction requirement, not as a result of the §102(b) rejection.

Claims 81 and 117, and their respective pending dependent claims contain a claim element of treating an aqueous slurry of soy protein material with an enzyme preparation containing an acid phosphatase enzyme to degrade ribonucleic acids in the soy protein material.

The EP 0 380 343 reference teaches the use of one or more phytate degrading enzymes to degrade phytates and phytic acid in a soy protein material, where acid phosphatase and phytase are two enzymes disclosed as useful as phytate degrading enzymes. EP 0 380 343 does not disclose ribonucleic acids or the use of an enzyme to degrade ribonucleic acids in a soy protein material. Therefore, EP 0 380 343 does not explicitly anticipate the claims.

EP 0 380 343 also does not inherently anticipate the claims. In order to inherently anticipate the claims, the process of the EP reference must necessarily result in the method as claimed in claims 81-93 and 96-124. See e.g *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981) (inherency may not be established by probabilities or possibilities—the mere fact that a certain thing may result from a given set of circumstances is not sufficient); *Mehl/Biophile International Corp. v. Milgraum*, 52 USPQ2d 1303, 1307 (CAFC 1999)(for a claim element to be anticipated inherently by a reference the element must be a necessary consequence of what was deliberately intended as disclosed in the prior art reference).

The EP 0 380 343 reference does not inherently anticipate the claims since the reference is not limited to the use of an acid phosphatase enzyme to degrade phytates and phytic acid in a soy protein material. A detailed explanation of Applicants' position is set forth in their response of July 2, 2003. In short, the phytate reducing enzyme of the EP reference may be an acid phosphatase, but it is not limited to acid phosphatase, and it may be another phytate degrading enzyme such as phytase. One skilled in the art is presented with a choice of phytate degrading enzymes to practice the process of the EP reference. As shown in the Declaration of Theodore Wong filed with the response of July 2, 2003, a phytase enzyme such as NATUPHOS® is effective to degrade phytates and phytic acid in a soy protein material in accordance with the EP reference, but does not degrade ribonucleic acids. As such, the process of the EP reference does not necessarily result in the degradation of ribonucleic acids in a soy protein material, and the claims are not inherently anticipated by the reference. Claims 81-93 and 96-124, therefore, are not explicitly nor inherently anticipated by the EP reference.

The Patent Office apparently maintained the previous rejection over the Applicants' response of July 2, 2003 on the basis, in part, that "Applicants' argument that an acid phosphatase enzyme is not clearly disclosed is not deemed persuasive". Applicants, however, do not, and did not, argue that an acid phosphatase enzyme is not clearly disclosed in the EP reference—it clearly is disclosed (see e.g. EP 0 380 343, page 6, line 19.). Applicants contend instead that even though use of an acid phosphatase enzyme to degrade phytates and phytic acid in a soy protein material is disclosed in the EP reference, the process of the EP reference can be practiced without an acid phophatase

enzyme, and, therefore, the EP reference does not inherently anticipate the claims of the present application because degradation of ribonucleic acids in a soy protein material is not a necessary result of treating the soy protein material with a phytate-degrading enzyme as disclosed in the EP reference.

Applicants have shown that the process of the EP reference can be practiced without degrading ribonucleic acids in a soy protein material as a necessary consequence of practicing the EP process (*see* the Declaration of Theodore Wong filed with Applicants' Response of July 2, 2003). Specifically, Applicants have shown that the use of a phytase enzyme, as disclosed for example in the EP reference on page 6 line 19, in the process of the EP reference will produce a soy protein material product having a low phytate and phytic acid content in accordance with the intent of the EP reference, without degrading ribonucleic acids in the soy protein material.

The Patent Office apparently misapprehends the showing made in the Declaration of Theodore Wong that the phytase enzyme NATUPHOS® can be used to practice the process disclosed in the EP reference without reducing ribonucleic acids. Specifically, in the Office Action of January 28, 2004 (page 6) the Patent Office makes the statement "the declaration is directed to a comparison of some other enzyme preparation which is not disclosed in the EP reference." While the particular trademarked enzyme product NATUPHOS® is not disclosed in the EP reference, NATUPHOS® is a phytase enzyme, and phytase enzymes are very clearly disclosed in the EP reference as enzymes useful to practice the process of the EP reference. Specifically, the EP reference discloses that the phytate-degrading enzymes useful for degrading phytates and phytic acids in the process of the EP reference include **phytase** and acid phosphatases (page 6, line 19). Applicants' used NATUPHOS® as an example of a phytase enzyme that is effective to practice the process of the EP reference without degrading ribonucleic acids, thereby showing that the EP reference does not inherently anticipate the claims. One skilled in the art would not interpret the EP reference to be limited to only those enzymes identified by their trade names merely because the EP reference does not disclose the commercial trade names of any or all phytase enzymes useful in the process of the EP reference. Applicants could very well have written the Declaration to state that "a phytase enzyme" was used in the process of the EP reference without identifying the trade name of the enzyme as

NATUPHOS®. The fact that the specific trade name of the phytase is not disclosed in the EP reference is irrelevant because the EP reference discloses the use of phytases as a general class of enzymes useful to practice the process disclosed in the EP reference and NATUPHOS® is a phytase enzyme.

The Patent Office also maintained the §102(b) rejection, in part, because "Applicants have not shown that FINASE does not degrade acid phosphatase and the declaration is directed to a comparison of some other enzyme preparation which is not disclosed by the EP reference" (page 6 of the January 28, 2004 Office Action). Applicants assume that the Patent Office meant to state that "Applicants have not shown that FINASE does not degrade ribonucleic acids...", since FINASE is an acid phosphatase containing enzyme preparation rather than an enzyme used to degrade acid phosphatase enzymes. Applicants never attempted to prove that acid phosphatase enzyme preparations, including FINASE, are ineffective to degrade ribonucleic acids in a soy protein material. The subject matter of the present invention is the use of an acid phosphatase enzyme preparation to degrade ribonucleic acids in a soy protein material—it would make no sense for Applicants to attempt to prove otherwise. As discussed above Applicants have shown that the process of the EP reference can be practiced without degrading ribonucleic acids in a soy protein material or reducing the level of ribonucleic acids in a soy protein material, therefore the EP reference does not inherently anticipate the claimed invention.

It is the Patent Office's burden to initially establish inherent anticipation, not the Applicants' burden to initially disprove it. In relying upon the theory of inherency, the Patent Office must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy*, 17 USPQ2d 1461 (BPAI 1990). The basis provided by the Patent Office—that the EP reference teaches the use of an acid phosphatase enzyme to degrade phytates and phytic acid in a soy protein material—is insufficient to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from teachings of the EP reference. The EP reference teaches a process in which a phytate-degrading enzyme, which can be a phytase or an acid phosphatase, is used to degrade phytates and phytic acid in a soy protein material.

The Patent Office has provided no basis in fact and/or in technical reasoning that reasonably supports a determination that the process disclosed by the EP reference, in its entirety, necessarily results in the degradation of ribonucleic acids in a soy protein material—specifically, the Patent Office has provided no proof that phytase enzymes are effective to degrade ribonucleic acids in a soy protein material. The Patent Office cannot pick and choose pieces of the EP reference to meet its burden to establish inherent anticipation because inherency cannot be established by possibilities or probabilities, it must occur inherently as a result of the process disclosed in the EP reference in its entirety. See *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981). Therefore, the Patent Office has failed to establish a basis in fact or in technical reasoning supporting a determination of inherency.

Applicants' fail to understand the relevance of the Patent Office's statement that, with respect to the inherent anticipation case law *Mehl/Biophile International Corp.*, "it should be noted that the case was directed to hair material and not a soy protein material." Applicants' cited the case for its common law *stare decisis* effect: the rule of law enunciated in the case is important, not the actual fact situation that led to the ruling. The fact that *Mehl/Biophile International* dealt with hair depilation does not mean the rule of law stated in the case is inapplicable to other fact situations not involving hair depilation. To hold otherwise would eviscerate the common law system on which American jurisprudence is founded. As such, the rule of law set forth in the *Mehl/Biophile International* case by the Federal Circuit, a court having judicial precedential authority over the Patent Office, applies to the present patent application—namely, a claim element is inherently anticipated by a reference only when the claim element is a necessary consequence of the deliberate intent of the reference (whether the claim element is directed to hair depilation or a soy protein material).

In the Office Action of January 28, 2004, claims 81-125 were rejected under 35 USC §103(a) as being obvious over EP 0 380 343. Applicants respectfully traverse the rejection.

Claims 94, 95, and 125 have been cancelled, claim 125 having been cancelled in response to the restriction requirement, not as a result of the §103(a) rejection.

Claims 81 and 117, and their respective pending dependent claims, are not obvious over the EP reference because nothing in the EP reference would direct one skilled in the art to attempt to degrade ribonucleic acids in a soy protein material with an acid phosphatase enzyme.

As noted above, the EP reference never mentions ribonucleic acids at all. As such, one skilled in the art would not even consider the EP reference when considering how to degrade ribonucleic acids in a soy protein material. The Patent Office attempts to establish a *prima facie* case of obviousness by stating that the degradation of phytates as disclosed would also guide one of skill in the art to degrade other components such as RNA, if so desired; and that the effect of degrading phytates would be the same effect for RNA using the same enzyme, acid phosphatase.

The Patent Office, however, fails to establish a *prima facie* case of obviousness. The conclusion the Patent Office reaches on page 6 that "enzymes behave differently with different substrates" succinctly states why one of skill in the art would not find claims obvious over the EP reference for the reasons asserted by the Patent Office. The Patent Office's attempt to establish a *prima facie* case of obviousness over the EP reference is based on upon the supposition that enzymes that are effective to remove phosphorous groups from phytates (and other mono-phosphoester compounds) would be expected by one skilled in the art to degrade ribonucleic acids (polymeric diphosphoester compounds), which also contain phosphorous groups. One of skill in the art, however, would recognize that there is a significant difference between enzymatic degradation of non-polymeric, mono-phosphoester phosphorus containing compounds such as phytates and phytic acid, and degrading a polymeric diphosphoester-linked nucleotide such as ribonucleic acid with an enzyme. Mono-phosphatase enzymatic activity in polymeric ribonucleic acids is inhibited relative to enzymatic activity in monomeric nucleotides, phytates, and phytic acid by factors introduced by the polymeric structure of the ribonucleic acid and, more importantly, by the fact that mono-phosphatase enzymes are known to cleave mono-phosphoester bonds not diphosphoester bond linkages such as those in ribonucleic acids. Enzyme inhibitory factors introduced by the polymeric structure of RNA include steric hindrance, covalent blockage of an enzyme's site of

activity, conformational blockage of the substrate upon which the enzyme acts, and conformational disruption of substrate sterochemistry required for enzyme activity.

As shown in Leach et al, *Am J Clin Nutr*, 1995; 61:1224-30 (particularly p. 1224, 2d col. 1st paragraph; and p. 1226, Figure 1) (attached as Exhibit A) one skilled in the art would not expect phosphatases to degrade polymeric nucleotides such as ribonucleic acids, but rather would expect polymeric nucleotides to be degraded by phosphodiesterase enzymes such as ribonucleases and deoxyribonucleases (nucleases). As further shown by Leach et al one skilled in the art would expect phosphatases to be effective to degrade only mono-phosphoester compounds such as monomeric nucleotides and phytates. In short, polymeric ribonucleic acids are a fundamentally different type of compound from monomeric phytates, and one skilled in the art would not expect a phosphatase that is effective to degrade phytates to degrade ribonucleic acids merely because both contain phosphoesters—especially when each contains a different type of phosphoester and the enzymes' site of activity is the phosphoester itself (ie. the phytate degrading enzyme behaves differently with a ribonucleic acid substrate than it does with phytate substrate).

The Declaration of Theodore Wong filed in the response of July 2, 2003 serves as proof of the above argument. The Declaration shows that a phytase enzyme is effective to cleave mono-phosphoester bonds and thereby reduce phytate and phytic acid in a soy protein material, yet is ineffective to degrade ribonucleic acids in the soy protein material. One of skill in the art would recognize that enzymes behave differently with different substrates and would not expect a phytate-degrading enzyme to be effective to degrade a ribonucleic acid. Applicants have clearly shown, therefore, that the Patent Office has failed to establish a *prima facie* case of obviousness based on the EP reference.

In light of the above, Applicants respectfully request allowance of all the remaining pending claims 81-93 and 96-124.

Respectfully submitted,

WONG ET AL

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